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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,098	02/27/2004	Shaun Jordan	Q-69854	8004

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/787,098	JORDAN ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 30, 2005 has been entered.

Claim 1 is pending. Applicant's remarks filed December 30, 2005 are addressed below to the extent they are relevant to the new rejections made in this office action,

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 is drawn to a congenic rat comprising a mutant GPR10 gene, wherein said congenic rat is obtained by crossing an OTELF rat with a wild type rat, and wherein said congenic rat exhibits prolonged immobilization time when assayed in a forced swim test compared to said wild type rat and anti-anxiety behavior in an elevated plus-maze test compared to a wild type rat.

The claimed rat is not enabled because the rat does not meet the art-recognized definition of congenic. The specification discloses that OLETF rats, comprising a naturally occurring mutant GPR10 gene, were mated with BN rats to produce N1 rats (page 45, lines 26-28). The N1 rats were then backcrossed to the BN rats to produce N2 rats (page 45, line

33 to page 46, line 1). This backcrossing took place for five generations (page 46, lines 1-8). N5 rats were mated with each other to produce a homozygous congenic rat (page 46, lines 11-13). The art, however, teaches that at least 10 generations of backcrossings are needed to produce congenic rats. Rat Strains were considered at the time of filing to be congenic when a minimum of 10 backcross generations to the background strain have been made (http://imgt.cines.fr/textes/IMGTrepertoireMHC/Polymorphism/strains/Consomic-Congenic.html; Silver (1995), page 1, parag. 5, lines 5-8; Cowley, page 47, col. 2, lines 15-21). Further the art taught that brother – sister matings of the N10 generation were used to produce congenic rats (Silver, page 1, parag. 6, lines 3-5). Applicant's rats were backcrossed 5 time before heterozygotes were mated, and the final matings are not disclosed to be brother sister matings. Thus, the claimed rat does not appear to congenic as defined in the art.

The art taught at the time of filing, strain differences of rats affected anxiety related behavior (Rex, page 107, col. 2, lines 5-7). The present invention is to a congenic rat, where a Long-Evans rat gene has been introduced into a BN (Brown Norway) rat background. However, the behavioral differences observed could be due to a Long-Evans gene contained on the same locus as the mutant gene. Thus, the results obtained using the OLETF rat x BN rat congenic strain in the elevated-plus maze test or the forced swim test does not necessarily reflect a mutant GRP10 function. Rather, the results may reflect an inherent parental rat trait, or other confounding gene. Ramos states "inbred strains of rodents, which have not been selective for emotionality, may show striking differences in regard to a range of different emotional responses" (Ramos, page 45, col. 2, parag. 4, lines 1-4). With regard to the forced swimming test, MR rats were more immobile than MNR rat (Ramos, page 47, parag. 1, lines 5-10). When the rats were tested in the elevated plus maze, the MNR rats spent more time in the open arms than the MR rats (Ramos, page 47,

col. 1, parag. 1, lines 12-15). Other rat strains showed variation in the elevated plus maze: LEW rats spent less time in the open arms of the elevated plus maze that SHR rats visited the open arms of the elevate plus maze more often than WKY rats (Ramos, page 48, col. 2, parag. 2, lines 8-10). Also, test results for anxiety are not consistent across all testing. Rats considered not stressed by certain tests will no necessarily behave as not stressed on other tests (Ramos, page 50, col. 1, parag. 1, lines 3-9). WKY rats have been proposed as a rat model for depressive behavior because they are most susceptible to developing learned helplessness and demonstrates higher levels of immobility at baseline forced swimming tests (Cryan, page 561, col. 2, parag. 1). In the forced swimming test, WKY rats showed dramatically enhanced depressive behavior as compared to Spraque-Dawley rats (Cryan, page 561, col. 2, parag. 2, lines 1-7). While the forced swimming test and the elevated plus maze test are accepted, at least in drug studies, for determining depression and anxiety, the vast strain differences in response to these test among rat strains indicates that test results obtained for the congenic rat claimed, could be due the genetic background of the congenic rat.

It is not evident that the claimed congenic rat was enabled at the time of filing because the rat does not meet the art recognized criteria for "congenic" and rat strain variability raises the issue that the behavioral difference observed could be due to the genetic background of the claimed rat. Thus at the time of the instant invention, the skilled artisan would have needed to engage in an undue amount of experimentation without a predictable degree of success to implement the claimed invention.

Applicant argues that there is confusion on the examiner's part as to the wild type control rats used in the forced swimming and elevated-plus maze tests. However, a review of examples 4 and 5 show no mention of the control rats other a to say they are wild type. The particular strain is not mentioned. The differences in strains in each of these tests,

documented in the art, would require that controls be the parents. While at page 7, the wild type rat is suggested to be a BN or F344 rat. However, the enablement rejection remains because of the strain variability and genetic background of the rats disclosed as discussed above. Applicant is invited so show support for the control rats being of the same generation as the -/- rates.

The claims are free of the prior art. At the time of filing, the art did not teach or suggest a congenic rat comprising a mutant GPR10 gene, wherein said congenic rat is obtained by crossing an OTELF rat with a wild type rat, and wherein said congenic rat exhibits prolonged immobilization time when assayed in a forced swim test compared to said wild type rat and anti-anxiety behavior in an elevated plus-maze test compared to a wild type rat.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

March 8, 2006